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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,973	08/22/2001	Timothy P. Croughan	98A9-USC1 Croughan	8353

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PATENT DEPARTMENT  
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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

**Office Action Summary**

Application No.

09/934,973

Applicant(s)

CROUGHAN, TIMOTHY P.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 62-73 and 75-81 is/are pending in the application.
- 4a) Of the above claim(s) 63,65,67,69,71-73,76,78 and 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 62,64,66,68,70,75,77,79 and 81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Remarks filed 13 May 2003.
2. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
3. The information disclosure statement filed 13 May 2003 has been considered, a signed copy is attached hereto.
4. Applicant's statement on page 12, section 12 of the response is deemed sufficient to enable a Deposit of Biological material for the purposes of enablement under 35 USC § 112, first paragraph.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

6. Claims 63, 65, 67, 69, 71-73, 76, 78 and 80 remain withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4, filed 14 January 2003.
7. This application contains claims 63, 65, 67, 69, 71-73, 76, 78 and 80 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

9. Applicant's statement as directed to rejoinder of process claims under 37 C.F.R. § 1.121 at the time of allowance is noted (pages 2-3 of the Remarks).

***Claim Rejections - 35 USC § 112***

10. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 February 2003. Applicant's arguments filed 13 May 2003 have been fully considered but they are not persuasive.

Applicant argues that the specification in fact describes a correlation between the structure and the function of the whole organism (paragraph spanning pages 7-8 of the Remarks). Applicant argues that the specification describes, in detail, the actual reduction to practice of twenty-seven species of herbicide resistant rice in accordance with the present invention (page 8, 4<sup>th</sup> paragraph of the Remarks). This argument is not

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found to be persuasive because Applicant does not describe what mutations in the rice AHAS enzyme has occurred to produce herbicide tolerance. The art recognizes that there are multiple mutations that can lead to AHAS enzyme herbicide tolerance, and without sufficient guidance, one of skill in the art cannot determine what Applicant has described.

Applicant argues that before the present invention was reduced to practice no source of AHAS herbicide resistance in rice was known that satisfy the functional limitations of the claimed invention (page 10, 1<sup>st</sup> paragraph of the Remarks). This argument is not found to be persuasive given the disclosure of Terakawa *et al* (1992) cited in the previous Office action.

Applicant argues that one should readily be able to determine the ancestry of a rice variety accused of infringing [these] the claims (page 11, 2<sup>nd</sup> paragraph of the Remarks). Applicant argues that, as directed to ATCC 75295, the patent law imposes no requirement that an inventor must understand why an invention works, it suffices that the invention does in fact work (page 11, 3<sup>rd</sup> paragraph of the remarks). These arguments are not found to be persuasive because as directed to determining ancestry of a rice variety, Applicant makes the assumption of diligence of a third party. In addition, without knowing the genetic reason for resistance in ATCC 75295, one cannot determine a derived plant or herbicide resistance characteristics.

11. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 February 2003. Applicant's arguments filed 13 May 2003 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches one of ordinary skill in the art how to distinguish the claimed plants from other herbicide-resistant rice plants without undue experimentation (page 12, last paragraph of the Remarks). This argument is not found to be persuasive because AHAS resistance to an herbicide can occur via multiple mutations, either single amino acids or multiple amino acids, none of which Applicant has taught in the exemplified rice plants. In addition, given the negative limitation in claim 62, Applicant invites experimentation to identify the relevant mutation in ATCC accession number 97523 AHAS enzyme and to identify progeny of said 97523 rice plant comprising the same herbicide resistance characteristics.

As directed to the rejection of claim 81, Applicant argues that said claim specifically requires that the plant in question must be a derivative of the plant with ATCC accession number 75295 and that claim 81 requires that the rice plant must among other things have herbicide resistance characteristics that may be traced back to the deposit line ATCC 75295 (paragraph spanning pages 14-15 of the Remarks). This argument is not found to be persuasive because there is no such limitation in claim 81, it only requires that the claimed rice plant have the herbicide resistance characteristics of the deposit line ATCC 75295, not that said characteristics are inherited from said deposit line. Here again Applicant is inviting experimentation to determine the herbicide

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resistance characteristics of deposit line ATCC 75295, not taught by Applicant, so that one of skill in the art would know what is being claimed and/or what would be infringing upon Applicant's claimed invention.

***Claim Rejections - 35 USC § 102***

12. Claims 62, 64, 66, 68 and 70 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275). This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 February 2003. Applicant's arguments filed 13 May 2003 have been fully considered but they are not persuasive.

Applicant argues that Terakawa *et al* do not disclose an herbicide-resistant rice plant wherein the growth of said herbicide-resistant plant is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of the rice plant and that bensulfuron methyl does not normally inhibit the growth of a rice plant (page 15 of the Remarks). This argument is not found to be persuasive because Terakawa *et al* disclose at page 268, first paragraph, that "BSM toxicity to rice is not severe, it affects to the initial growth of the rice plants", but "severe" and "would normally inhibit the growth of the rice plant" are relative limitations depending upon the rate of herbicide application. Terakawa *et al* clearly disclose that at a rate of 0.03 mM BSM the mutant rice plants are resistant to a level that would inhibit the growth of a rice plant (see page 271, Tables 2 and 3).

Applicant argues that the possibility of misuse or of side effects does not<sup>†</sup> make the herbicide one "that would normally inhibit the growth of a rice plant" as required by

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independent claim 62 (paragraph spanning pages 15-16 of the Remarks). This argument is not found to be persuasive because the intended use of an herbicide does not obviate the rejection, the fact that a higher rate of herbicide is required to "normally inhibit the growth of a rice plant" does not obviate the fact that Terakawa *et al* disclose a rice plant meeting all of the limitations of the rejected claims.

Applicant's argument directed to the use of bensulfuron methyl as an herbicide on pages 16-17 of the Remarks have been considered but are viewed by the Examiner as irrelevant to the instant rejection for the reasons given supra.

As directed to claim 64, limited to imidazolinone herbicide resistance of the AHAS enzyme in rice, Applicant's own evidence supports that sulfonylurea herbicide resistant rice plants comprising an herbicide resistant AHAS enzyme are also resistant to imidazolinone (Table 2, pages 16-18 of the specification).

The limitation "mutation-inducing conditions" at claim 70 does not distinguish the claimed rice plant from that of the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

### ***Claim Rejections - 35 USC § 103***

13. Claims 75, 77 and 79 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Croughan 1994 (Louisiana Agriculture 37(3): 25-26) in view of Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275). This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 February 2003.



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Applicant's arguments filed 13 May 2003 have been fully considered but they are not persuasive. Claims 62, 64, 66, 68 and 70 are withdrawn from this rejection in view of the rejection under 35 USC § 102(b) above.

Applicant's arguments as directed to the teachings of Terakawa are addressed above (page 18, 3<sup>rd</sup> paragraph of the Remarks).

Applicant argues that Croughan 1994 does not specifically teach that the isolated herbicide-resistant rice plant has a herbicide-resistant AHAS enzyme (page 18, 4<sup>th</sup> paragraph of the Remarks). Applicant also argues that the herbicide-resistant rice discussed in Croughan 1994 is the same as that which was deposited with the ATCC with accession number 75295, and that in 75295 the mechanism of herbicide resistance is still unknown, however that resistance is affirmatively known not to result from a resistant AHAS enzyme (pages 18-19 of the Remarks). This argument is not found to be persuasive because the purpose of the teachings of Croughan 1994 is that of producing rice plant with resistance to AHAS inhibitory herbicides. Terakawa *et al* teaches that such herbicide resistance can be found in rice plants having a resistant AHAS enzyme. Terakawa *et al* also teach that multiple/non-identical ALS (syn. AHAS) enzyme encoding genes can be mutated in a plant to give herbicide resistance and Terakawa *et al* motivates one of ordinary skill in the art to produce such rice plants (see paragraph spanning pages 273-274).

#### ***Double Patenting***

14. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 1-9 of U.S. Patent No. 5,773,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued Patent teach a herbicide-resistant rice plant that has the herbicide resistance characteristics of the plant deposited with ATCC accession number 97523. Because the issued claims do not limit the number of generations away from said deposited plant, the herbicide-resistant rice plant of the instant claims would be obvious, because one of ordinary skill in the art would not be able to distinguish the "derivative" plant of the patented herbicide-resistant rice plant from the "derivative" plant of the instant claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 February 2003. Applicant's arguments filed 13 May 2003 have been fully considered but they are not persuasive.

Applicant argues that the last limitation of claim 62 excludes derivative of the plant with ATCC accession number 97523, and that it is a nearly universal practice in the art that the developer or breeder of a new rice cultivar will disclose publicly the ancestry of the variety (page 21 of the Remarks). This argument is not found to be persuasive because Applicant does not teach in the '704 patent or the instant application what mutation the '97523' rice plant comprises and how to distinguish its progeny from any other rice plant having a mutant AHAS enzyme that is resistant to an herbicide. In addition the instant application does not share continuity with the '704 patent, and the '704 patent teaches how to make other rice plants having a mutant AHAS enzyme that is resistant to an herbicide.

Applicant argues that claim 62, of the instant application, expressly excludes derivatives of ATCC 97523, thus claim 62 of the present application and claim 1 of the '704 patent are disjoint. Applicant also argues that nothing in claim 1 of the '704 patent teaches or suggests any herbicide resistant rice having a resistant AHAS enzyme, other than the specific source of resistance from ATCC 97523 and there is no suggestion for how to make such a plant, and there would have been no reasonable expectation that such a plant could be successfully produced (page 24 of the Remarks). This argument is not found to be persuasive because the '704 patent clearly teaches that mutant AHAS enzymes were known to those of ordinary skill in the art at the time of Applicant's invention, in general, to confer herbicide-resistance to plants (see column 2). In addition, one of ordinary skill in the art would have had a reasonable expectation of success in producing other rice plants having a herbicide-resistant AHAS enzyme given the teachings of the '704 patent.

### ***Conclusion***

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



**AMY J. NELSON, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

David H. Kruse, Ph.D.  
22 July 2003